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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/051,685	08/19/98	SANDERSON	UNMC63102

000110 HM22/1108
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EXAMINER	
VANDER VEGT, F	
ART UNIT	PAPER NUMBER
1644	13

DATE MAILED: 11/08/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
09/051,685

Applicant(s)
Sanderson et al

Examiner
F. Pierre VanderVegt

Group Art Unit
1644



☒ Responsive to communication(s) filed on Jun 9, 2000

☐ This action is FINAL.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire three month(s), ~~or thirty days, whichever is longer~~, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claim

☒ Claim(s) 1-17 and 25 ~~is/are~~ pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 1, 2, 6, 7, 10-14, 16, 17, and 25 ~~is/are~~ rejected.

☒ Claim(s) 3-5, 8, 9, and 15 ~~is/are~~ objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

This application claims priority to provisional application 60/005,727 and PCT/US96/16825.

Page 1 of the specification should be amended to properly identify the priority applications.

Claims 18-24 have been canceled.

Claims 1-17 and 25 are currently pending in this application.

Election/Restriction

1. In view of Applicant's response filed June 9, 2000, the species requirement is hereby withdrawn and claims 8 and 9 are hereby rejoined with claims 1-7 and 10-17.

2. In view of the amendment filed June 9, 2000, no outstanding rejections are maintained.

3. The following is a new ground of rejection and this Office Action is made NON-FINAL.

Claim Rejections - 35 USC § 112

4. Claims 1, 2, 6, 7, 10-14, 16 and 17 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The scope of the claims, drawn to molecular adjuvants where the targeting moiety is covalently linked to the immunogen, includes in scope a number of embodiments for which there is no sufficient written description in the specification. Claim 1 recites "a targeting ligand having binding affinity for a characteristic determinant of an antigen presenting cell" in lines 3-4. Antigen presenting cells are conventionally identified in the art by the co-expression of a number of markers, many of which are present on other cell types or at different developmental stages. The term "characteristic determinant" is defined in the instant specification as "an epitope (or group of

epitopes) that serves to identify a particular population of antigen presenting cells and distinguish it from other antigen presenting cell populations" (page 13, for example). This definition includes markers or cell specific determinants which are not directly involved in the antigen capture/processing/presentation pathway and there is no descriptive support in the specification for the molecular adjuvant to be effective when binding such uninvolved determinants. *Vas-Cath Inc. v. Mahurkar* ((CAFC, 1991) 19 USPQ2d 1111), clearly states that "Applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the 'written description' inquiry, whatever is now claimed." (See *Vas-Cath* at page 1117). The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See *Vas-Cath* at page 1116). It is respectfully submitted that the instant specification does not describe a sufficient number of species to provide full descriptive support of the genus encompassing all such molecular adjuvants.

Therefore only the disclosed species of molecular adjuvants, i.e., those which bind C5a receptor, IFN-gamma receptor, CD21 receptor, CD64 receptor and CD23 receptor, but not the full breadth of the claims meets the written description provision of 35 USC 112, first paragraph.

Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 USC 112 is severable from its enablement provision (see *Vas-Cath* at page 1115).

5. Claim 25 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention.

Claim 25 is dependent upon claim 24, which is a canceled claim.

Allowable Subject Matter

6. Claims 3-5, 8, 9 and 15 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.


Conclusion

7. The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which Applicant may become aware in the specification.

8. Papers related to this application may be submitted to Technology Center 1600, Group 1640 by facsimile transmission. Papers should be faxed to Group 1640 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The fax phone number for official documents to be entered into the record for Art Unit 1644 is (703)305-3014.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to F. Pierre VanderVegt, whose telephone number is (703)305-6997. The Examiner can normally be reached Tuesday through Friday and odd-numbered Mondays (on year 2000 366-day calender) from 6:30 am to 4:00 pm ET. A message may be left on the Examiner's voice mail service. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Ms. Christina Chan can be reached at (703)308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist, whose telephone number is (703)308-0196.

F. Pierre VanderVegt, Ph.D.
Patent Examiner
Technology Center 1600
November 7, 2000



F. PIERRE VANDERVEGT
PATENT EXAMINER